UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF MASSACHUSETTS

EASTERN DIVISION

KATE WEISSMAN, Plaintiff, v. UNITEDHEALTHCARE INSURANCE COMPANY, UNITED HEALTHCARE SERVICE, LLC, AND INTERPUBLIC GROUP OF COMPANIES, INC. CHOICE PLUS PLAN, Defendants.	**CIVIL ACTION NO. 1:19-cv-10580** **Consolidated with 1:19-cv-12224; and** **Consolidated with 1:19-cv-12239** **CLASS ACTION** **CONSOLIDATED FIRST AMENDED COMPLAINT**
RICHARD COLE, on behalf of himself and others similarly situated, Plaintiff, v. UNITEDHEALTHCARE INSURANCE COMPANY, Defendant.	CIVIL ACTION NO. 1:19-cv-12224
ZACHARY RIZZUTO, Plaintiff, v. UNITEDHEALTHCARE INSURANCE COMPANY, UNITEDHEALTHCARE SERVICES, INC., and THE HERTZ CUSTOM BENEFIT PROGRAM, Defendants.	CIVIL ACTION NO. 1:19-cv-12239

Plaintiffs Kate Weissman, Richard Cole, and Zachary Rizzuto bring this action as individuals and on behalf of all other similarly situated ("the PBRT Class Members") against Defendants UnitedHealthcare Insurance Company and UnitedHealthcare Services, LLC (collectively "UnitedHealthcare"), and Interpublic Group of Companies, Inc. Choice Plus Plan and The Hertz Custom Benefit Program (collectively "the Plans"), pursuant to the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001 *et seq.* ("ERISA") and Rule 23 of the Federal Rules of Civil Procedure, and allege as follows:

NATURE OF THE ACTION

1. Plaintiffs bring this action on behalf of themselves and those similarly situated to challenge UnitedHealthcare's deceptive and fraudulent misrepresentations to its ERISA plan participants and beneficiaries that it would deliver access to covered, medically necessary healthcare for the treatment of cancer. Further, Plaintiffs bring this action to challenge UnitedHealthcare's deceptive and unfair administration of its ERISA plans, including its prior authorization and utilization review process for plan members seeking Proton Beam Radiation Therapy ("PBRT"), and its adjudication and administration of claims for PBRT made under ERISA plans underwritten and administered by UnitedHealthcare.

2. UnitedHealthcare has developed and uniformly applies an arbitrary internal coverage medical policy to purposefully and arbitrarily narrow and restrict the scope of coverage for PBRT in a manner that is inconsistent with generally accepted standards of care. UnitedHealthcare applies this uniform medical policy to deny PBRT requests as experimental, investigational, or unproven, despite UnitedHealthcare's institutional knowledge of the overwhelming, long-standing and decades-old recognition by the medical community that PBRT is an established, effective and medically appropriate form of treatment for cancer.

3. Instead of acting solely in the interests of the participants and beneficiaries of its health insurance plans, upon information and belief, UnitedHealthcare denied coverage for PBRT to treat cancer because, on average, PBRT may be more expensive than traditional Intensity Modulated Radiotherapy ("IMRT") or other treatments, essentially placing profits over patient health and well-being.

THE PARTIES

4. Plaintiff Kate Weissman is a citizen of the Commonwealth of Massachusetts and resides in Suffolk County. Ms. Weissman is and was at all relevant times a participant in a group health plan governed by ERISA that is provided and funded by Ms. Weissman's employer, and administered by UnitedHealthcare, pursuant to which Ms. Weissman is entitled to health care benefits.

5. Plaintiff Richard Cole is a citizen of the State of Florida who resides in Miami-Dade County. Mr. Cole was at all relevant times a participant in a group health plan governed by ERISA that was sponsored by Mr. Cole's employer, and administered by UnitedHealthcare pursuant to which Mr. Cole was entitled to health care benefits.

6. Plaintiff Zachary Rizzuto is a citizen of the State of Florida and resides in Lee County. Mr. Rizzuto was at all relevant times a participant in a group health plan governed by ERISA that was provided and funded by Mr. Rizzuto's employer, and administered by UnitedHealthcare, pursuant to which Mr. Rizzuto was entitled to health care benefits.

7. Defendant UnitedHealthcare Insurance Company is and was at all relevant times a corporation duly organized and existing under the laws of the State of Connecticut, with its principal place of business located in Connecticut. UnitedHealthcare Insurance Company is authorized to conduct business as a health care plan provider and insurer, and transacts, and is

transacting, the business of providing, administering and insuring health plans to consumers in this judicial district.

8. Defendant UnitedHealthcare Service, LLC is and was at all relevant times a corporation duly organized and existing under the laws of the State of Delaware, with its principal place of business located in Wilmington, Delaware. UnitedHealthcare Service, LLC is authorized to conduct business as a health care plan provider and insurer, and transacts, is transacting, and is in the business of providing, administering and insuring health plans to consumers in this judicial district.

9. Defendant Interpublic Group of Companies, Inc. Choice Plus Plan ("the Interpublic Plan") is a self-funded group health plan organized and regulated under ERISA. The Plan Administrator is located in New York, New York. While the Interpublic Plan has delegated discretionary authority to UnitedHealthcare to decide whether a treatment or supply is covered and determine the amount of the eligible expense, the Interpublic Plan simply funds the payment of benefits.

10. Defendant The Hertz Custom Benefit Program ("the Hertz Plan") is a self-funded group health plan organized and regulated under ERISA. The Plan Administrator is located in Estero, Florida. While the Hertz Plan has delegated discretionary authority to UnitedHealthcare to decide whether a treatment or supply is covered and the amount of the eligible expense, the Hertz Plan simply funds the payment of benefits.

JURISDICTION AND VENUE

11. This action is brought under 29 U.S.C. §§ 1132(a), (e), (f), and (g) of ERISA, as it involves claims for breach of fiduciary duty and denial of benefits owed under employee benefit

health plans regulated and governed under ERISA. Jurisdiction is predicated under these Code sections as well as 28 U.S.C § 1331, as this action involves a federal question.

12. Ms. Weissman's claims in this action were specifically administered in this judicial district, and Ms. Weissman resides or may be found in this judicial district, the Eastern District of Massachusetts. Thus, venue is proper in this judicial district pursuant to 29 U.S.C. § 1132(e)(2) (special venue rules applicable to ERISA).

13. Mr. Cole filed his class action on April 3, 2019, in the U.S. District Court for the Southern District of Florida, the district in which Mr. Cole resides, where UnitedHealthcare denied Mr. Cole's PBRT pre-authorization request for coverage, and where he received PBRT treatment, with successful results.

14. On October 28, 2019, the Honorable Darrin P. Gayles granted UnitedHealthcare's motion to transfer (*Cole*, No. 1:19-cv-21258 (S.D. Fla.), ECF No. 28).

15. On April 8, 2020, this Court ordered the consolidation of Mr. Cole's action, *Cole v. UnitedHealthcare Insurance Company*, No. 1:19-cv-12224 (D. Mass), with Ms. Weissman's action pursuant to Fed. R. Civ. P. 42(a), and permitted Ms. Weissman to file an amended complaint by May 15, 2020, adding Mr. Cole as an additional putative class member (ECF No. 39).

16. Mr. Rizzuto filed his class action on September 19, 2019, in the U.S. District Court for the Middle District of Florida, the district in which Mr. Rizzuto resides and where UnitedHealthcare denied Mr. Rizzuto's PBRT pre-authorization request for coverage.

17. On October 28, 2019, the Honorable Sheri Polster Chappell granted UnitedHealthcare's motion to transfer (*Rizzuto*, No. 2:19-cv-00691 (M.D. Fla.), ECF No. 30).

18. On April 13, 2020, this Court ordered the consolidation of Mr. Rizzuto's action, *Rizzuto v. UnitedHealthcare Insurance Company, et al.*, No. 1:19-cv-12239 (D. Mass), with Ms.

Weissman's action pursuant to Fed. R. Civ. P. 42(a), and permitted Ms. Weissman to file an amended complaint by May 15, 2020, adding Mr. Rizzuto as an additional putative class member (ECF No. 39).

FACTUAL ALLEGATIONS

A. UnitedHealthcare Acts as a Fiduciary for its ERISA Plans

19. The majority of the health plans underwritten and administered by UnitedHealthcare are employee welfare benefit plans sponsored by private-sector employers and governed by ERISA ("ERISA plans").

20. During all relevant times, UnitedHealthcare acted as a fiduciary with respect to its administration of ERISA plans. In particular, UnitedHealthcare interpreted and applied ERISA plan terms, made coverage and benefit decisions under the ERISA plans within its sole discretion, and provided payment under the ERISA plans to participants/beneficiaries and their providers. Accordingly, UnitedHealthcare was required to comply with the requirements ERISA imposes on fiduciaries.

21. The health insurance plans administered by UnitedHealthcare are either fully insured or self-funded. With respect to fully insured plans, UnitedHealthcare both administers the plan by making all benefit determinations and pays the benefits out of its own assets. With respect to self-funded plans, UnitedHealthcare administers the plan, but the underlying plan sponsor or employer is ultimately responsible for paying for the promised healthcare benefits. When processing benefits for a self-funded plan, UnitedHealthcare makes all benefit determinations and authorizes benefit checks to be issued out of bank accounts that UnitedHealthcare controls on behalf of the sponsoring employers. Periodically, UnitedHealthcare will notify the sponsors of the self-funded plans of the need to replenish their accounts so that benefits can be paid.

UnitedHealthcare nevertheless continues to control these accounts and is fully responsible for processing the insurance claims and making the determination whether to issue a benefits payment check from these accounts.

22. UnitedHealthcare is a proper party for Plaintiffs and the putative PBRT Class to sue regardless of whether a particular ERISA plan is fully insured or self-funded, because UnitedHealthcare, not the underlying plan sponsor or employer, made and continues to make all the relevant decisions and exercised and continues to exercise the authority to issue benefit payment checks under the ERISA plans.

23. Plaintiffs and each of the putative PBRT Class Members have been denied access to and coverage for PBRT by UnitedHealthcare, and therefore sue UnitedHealthcare for denial of plan benefits and breach of fiduciary duty.

B. The Plans

1. The Interpublic Group of Companies, Inc. Choice Plus Plan

24. Plaintiff Kate Weissman is and was at all relevant times a beneficiary under the Interpublic Plan. The Interpublic Plan is a self-funded plan administered by the Plan Administrator, UnitedHealthcare, to whom the Plan Sponsor "has delegated to UnitedHealthcare the discretion and authority to decide whether a treatment or supply is a Covered Health Service and how the Eligible Expenses will be determined and otherwise covered under the Plan."

25. Beneficiaries under the Interpublic Plan have "the freedom to choose the Physician or health care professional [they] prefer," and they "can choose to receive Network Benefits or non-Network Benefits.

26. The Interpublic Plan "pays Benefits for therapeutic treatments …, including … intravenous chemotherapy or other intravenous infusion therapy and radiation oncology.

However, the Interpublic Plan limits coverage for "Covered Health Care Services" to those health care services that UnitedHealthcare deems to be "Medically Necessary."

27. The Interpublic Plan defines "Medically Necessary" as:

> **Medically Necessary -** health care services provided for the purpose of preventing, evaluating, diagnosing or treating a Sickness, Injury, Mental Illness, substance-related and addictive disorders, condition, disease or its symptoms, that are all of the following as determined by the Claims Administrator or its designee, within the Claims Administrator's sole discretion. The services must be:
> - In accordance with Generally Accepted Standards of Medical Practice.
> - Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for your Sickness, Injury, Mental Illness, substance-related and addictive disorders, disease or its symptoms.
> - Not mainly for your convenience or that of your doctor or other health care provider.
> - Not more costly than an alternative drug, service(s) or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your Sickness, Injury, disease or symptoms.

28. In addition, the Interpublic Plan includes a list of "Exclusions," which are deemed to be services that are not covered under the Interpublic Plan. One such Exclusion is entitled "Experimental or Investigational or Unproven Services" (the "Experimental Exclusion"), which is defined as follows:

> **Experimental or Investigational Services** - medical, surgical, diagnostic, psychiatric, mental health, substance-related and addictive disorders or other health care services, technologies, supplies, treatments, procedures, drug therapies, medications or devices that, at the time the Claims Administrator and the Plan Administrator make a determination regarding coverage in a particular case, are determined to be any of the following:
> - Not approved by the *U.S. Food and Drug Administration (FDA)* to be lawfully marketed for the proposed use and not identified in the *American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information* as appropriate for the proposed use.
> - Subject to review and approval by any institutional review

board for the proposed use. (Devices which are *FDA* approved under the Humanitarian Use Device exemption are not considered to be Experimental or Investigational.)

- The subject of an ongoing Clinical Trial that meets the definition of a Phase I, II or III Clinical Trial set forth in the *FDA* regulations, regardless of whether the trial is actually subject to *FDA* oversight.

(emphasis added.)

2. The Cole, Scott & Kissane, P.A. Plan

29. Plaintiff Richard Cole is and was at all relevant times covered by a health insurance plan issued on behalf of his employer, Cole, Scott & Kissane, P.A. (the "CSK Plan"). The CSK Plan is a fully insured plan, meaning that UnitedHealthcare both administers the CSK Plan by making all benefit determinations and pays the benefits out of its own assets. UnitedHealthcare maintains control over the decision-making process and is ultimately responsible for authorizing the issuance of checks for paying benefits.

30. As a participant in the CSK Plan, Mr. Cole was issued the Certificate of Coverage for the Health Savings Account Plan AHP3 of Cole, Scott & Kissane, P.A. ("Benefit Handbook"). The Benefit Handbook, which is a plan document governing Plaintiff's insurance that details the terms and conditions of the Employer Plan, defines "Covered Health Care Service(s)" as "health care services ... which [UnitedHealthcare] determine[s] to be ... Medically necessary."

31. The Benefit Handbook defines "Medically necessary" as "health care services provided for the purpose of preventing, evaluating, diagnosing or treating a Sickness, Injury, Mental Illness, substance-related and addictive disorders, condition, disease or its symptoms…."

32. In addition, the Benefit Handbook includes a list of "Exclusions," which are deemed to be services that are not covered under the Employer Plan. One such Exclusion is

entitled "Experimental or Investigational or Unproven Services" (the "Experimental Exclusion"). The Experimental Exclusion states as follows:

> [M]edical, surgical, diagnostic, psychiatric, mental health, substance related and addictive disorders or other health care services, technologies, supplies, treatments, procedures, drug therapies, medications or devices that, at the time [UnitedHealthcare] make[s] a determination regarding coverage in a particular case, are determined to be any of the following:
>
> - Not approved by the *US. Food and Drug Administration (FDA)* to be lawfully marketed for the proposed use and not identified in the *American Hospital Formula1y Service* or the *United States Pharmacopeia Dispensing Information* as appropriate for the proposed use.
> - Subject to review and approval by any institutional review board for the proposed use. (Devices which are *FDA* approved under the Humanitarian Use Device exemption are not Experimental or Investigational.)
> - The subject of an ongoing clinical trial that meets the definition of a Phase I, II or III clinical trial set forth in the *FDA* regulations, regardless of whether the trial is actually subject to *FDA* oversight.

(emphasis in original).

3. <u>The Hertz Custom Benefit Program</u>

33. Plaintiff Zachary Rizzuto is and was at all relevant times a beneficiary under The Hertz Custom Benefit Program ("the Hertz Plan"). The Hertz Plan is a self-funded plan administered by the Plan Administrator, UnitedHealthcare, to whom the Plan Sponsor has delegated to UnitedHealthcare the discretion and authority "to provide services in conjunction with claims review, processing and payment for [the Hertz Plan]."

34. The Hertz Plan pays benefits for therapeutic treatments, including "Chemotherapy and/or radiation therapy." However, the Hertz Plan limits coverage for "Covered Health Care Services" to those health care services that UnitedHealthcare deems to be "Medically Necessary."

35. The Hertz Plan defines "Medically Necessary" as:

> **Medically Necessary –** healthcare services provided for the purpose of preventing, evaluating, diagnosing or treating a Sickness, Injury, Mental Illness, substance use disorder, condition, disease or its symptoms, that are all of the following as determined by UnitedHealthcare or its designee, within UnitedHealthcare's sole discretion. The services must be:
>
> - In accordance with Generally Accepted Standards of Medical Practice;
> - Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for your Sickness, Injury, Mental Illness, substance use disorder disease or its symptoms;
> - Not mainly for your convenience or that of your doctor or other health care provider; and
> - Not more costly than an alternative drug, service(s) or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your Sickness, Injury, disease or symptoms.
>
> Generally Accepted Standards of Medical Practice are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying primarily on controlled Clinical Trials, or, if not available, observational studies from more than one institution that suggest a causal relationship between the service or treatment and health outcomes.

36. In addition, the Hertz Plan includes a list of "Exclusions," which are deemed to be services that are not covered under the Hertz Plan. One such Exclusion is entitled "Experimental or Investigational or Unproven Services" (the "Experimental Exclusion"), which is defined as follows:

> **Experimental and Investigational Services** – medical, surgical, diagnostic, psychiatric, substance abuse or other health care services, technologies, supplies, treatments, procedures, drug therapies or devices that, at the time UnitedHealthcare and Hertz make a determination regarding coverage in a particular case, are determined to be any of the following:
>
> - Not approved by the *U.S. Food and Drug Administration (FDA)* to be lawfully marketed for the proposed use and not identified in the *American Hospital Formulary Service or*

the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use,

- Subject to review and approval by any institutional review board for the proposed use, or
- The subject of an ongoing Clinical Trial that meets the definition of a Phase 1, 2 or 3 Clinical Trial set forth in the *FDA* regulations, regardless of whether the trial is actually subject to *FDA* oversight.

(Emphasis added.)

4. The PBRT Class Plans

37. At all times relevant, Plaintiffs Kate Weissman, Richard Cole, and Zachary Rizzuto and the members of the PBRT Class were covered by a health policy or plan, either self-funded or fully-insured, administered and/or insured by UnitedHealthcare (the "Class Plans"). The Class Plans, upon information and belief, contain the same material terms as the Plans specifically alleged herein.

38. In particular, the definition of "experimental and investigational" services or treatment in UnitedHealthcare**'s** health insurance policies at all relevant times has been substantially similar to the definition in the plans described above, and is interpreted by UnitedHealthcare as having the same meaning as comparable exclusions included in the UnitedHealthcare plans applicable to all Class Members.

C. Proton Beam Radiation Therapy

39. Contrary to UnitedHealthcare's systematic denial of PBRT as "experimental or investigational or unproven," PBRT is an established form of treatment that is widely accepted by physicians, government agencies, and many insurers and other payers, including Medicare and Medicaid (which by statute do not cover investigational or experimental services).

40. PBRT is a procedure that uses protons to deliver a curative radiation dose to a tumor, while reducing doses to healthy tissues and organs, which results in fewer complications

and side effects than traditional IMRT. With PBRT, protons deposit their energy over a very small area called the "Bragg peak." The Bragg peak can be used to target high doses of proton beams to a tumor, while doing less damage to normal tissues in front of and behind the tumor. Proton beams enable patients to tolerate higher total doses of radiotherapy compared with photons, which are used for traditional IMRT. The beam used in PBRT can be adjusted and shaped to match the size and shape of the cancerous tissue to be destroyed, while not killing healthy tissue beyond a pre-determined scope and depth. The cancer cell then begins to break itself down through a process known as apoptosis or programmed cell death.

41. The invention of PBRT is credited to Physicist Robert Wilson, who first described it theoretically in 1946. By the 1950's, some health care facilities were using PBRT to treat certain types of cancers. The Food and Drug Administration ("FDA") approved PBRT in 1988 for the treatment of cancer. The National Association for Proton Therapy, Alliance for Proton Therapy Access and other nationally-recognized medical organizations, and numerous meticulous peer-reviewed studies have validated the safety and effectiveness of PBRT. In addition to Plaintiffs' world-renowned treating providers, many other respected cancer facilities and providers, including Baptist Hospital's Miami Cancer Institute, MD Anderson Cancer Center, Loma Linda University, University of Florida, University of Maryland, Northwestern University, Mayo Clinic, Emory University, Case Western Reserve University, Washington University in St. Louis, University of Washington, New York Proton Center, and the Texas Center for Proton Therapy recommend and use PBRT on a regular basis.

D. UnitedHealthcare's PBRT Medical Policy No. T0132

42. UnitedHealthcare drafted and implemented the UnitedHealthcare PBRT Medical Policy No. T0132 (the "PBRT Policy"), based on demonstrably unreliable and outdated medical

evidence, purposefully ignoring updated and contemporary evidence definitively proving the medical efficacy of PBRT. UnitedHealthcare applies and employs the PBRT Policy to deem PBRT experimental or investigational, and therefore not covered for a variety of cancers, including cervical cancer, prostate cancer, and cancerous brain tumors, in persons that are 19 years of age or older.

43. As evidence of the arbitrary and capricious nature of UnitedHealthcare's denial of PBRT for treatment of cancer, the PBRT Policy maintains that PBRT is experimental or investigational, and therefore not covered, for persons 19 years of age or older, while simultaneously finding PBRT to be non-experimental and not investigational (i.e., proven safe and effective), and therefore always covered for persons under 19 years of age. There are no medical studies that support a conclusion that PBRT would be a proven, safe and effective treatment for the same cancer in one age group, but not the other.

44. As further evidence of the arbitrary and capricious nature of UnitedHealthcare's denial of PBRT for the treatment of cancer, the PBRT Policy either ignores the conclusions of specialty-society and medical community coverage guidelines, such as the American Society for Radiation Oncology (ASTRO) and the National Comprehensive Cancer Network, which provides a better barometer for the relevant medical community's recognition of PBRT as falling within generally accepted standards of medical practice for the treatment of cancer. Moreover, the PBRT Policy relies on outdated and unreliable scientific studies that in many instances are studies published several years prior to the requests for PBRT being adjudicated. This even though the scientific literature relating to PBRT is constantly updated on an annual basis across numerous publications.

45. On January 1, 2019, UnitedHealthcare changed its PBRT policy (the "New 2019 Policy"). The new policy acknowledges that PBRT is, in fact, not experimental for the treatment of prostate cancer. Under the New 2019 Policy, a person's request for authorization of PBRT to treat prostate cancer should be determined on a case-by-case basis as opposed to a blanket denial based on the PBRT Policy.

46. The revision and driving force behind the advent of the New 2019 Policy on January 1, 2019, appears entirely arbitrary from a scientific standpoint, as there were no significant clinical developments in PBRT cited in the New 2019 Policy.

47. Despite the change in policy, upon information and belief, UnitedHealthcare has continued to deny coverage of PBRT for the treatment of prostate cancer citing the old PBRT Policy.

48. UnitedHealthcare's breaches of its fiduciary duties unfairly forces its insureds, like Plaintiffs, to choose between receiving traditional therapy, like IMRT, which UnitedHealthcare will cover, but will also increase the risk of comorbidities[1], or paying out-of-pocket to receive the PBRT recommended by board certified oncologists that will spare healthy tissue and organs. Plaintiffs know that there are those less fortunate than them who cannot afford to have such a choice, and for this reason they bring this action on behalf of the PBRT Class Members as well.

E. Inapplicability of the Experimental Exclusion

49. The denials at issue relate to UnitedHealthcare's Experimental Exclusion and its application of the UnitedHealthcare PBRT Policy.

[1] "Comorbidity" refers to the simultaneous presence of two chronic diseases or conditions in a patient.

50. The Experimental Exclusion's first criterion – FDA approval – is inapplicable. As UnitedHealthcare acknowledges in its New 2019 Policy, radiation therapy is a procedure, and therefore, is not subject to FDA regulation.

51. The accelerators and other equipment used to generate and deliver PBRT, on the other hand, are regulated *and approved* by the FDA. On February 22, 1988, the FDA approved the Proton Therapy System, and designated it as a Class II Device for radiological treatment. This classification was codified at 21 C.F.R. § 892.5050, and describes the Proton Therapy System as a "device that produces by acceleration high energy charged particles (e.g., electrons and protons) intended for use in radiation therapy." Since at least February 22, 1988, PBRT no longer fit within the Plans' Experimental Exclusion.

52. The last two criteria under the Experimental Exclusion would not serve to exclude treatment for cancer. Clinical trials of PBRT may be ongoing but only to refine PBRT's use or to expand its use to treat other conditions, such as seizures. PBRT has long been recognized by the medical community as an established, medically appropriate treatment for the treatment of cancer, including cervical cancer, prostate cancer, and cancerous brain tumors.

53. PBRT also cannot be deemed "Unproven Services," defined in the Plans The definition states that unproven services are: "services ... that are determined not to be effective for treatment of the medical condition and/or not to have a beneficial effect on health outcomes due to insufficient and inadequate clinical evidence from well-conducted randomized controlled trials or cohort studies in the prevailing published peer-reviewed medical literature."

54. PBRT is not a "new" technology; it has been around and well-accepted for 30 years. PBRT has been determined to be "effective for treatment" of prostate cancer, and its use is entirely consistent with prevailing medical research, based on numerous "controlled trials or cohort studies

in the prevailing published peer reviewed medical literature." UnitedHealthcare persistently ignored such trials and studies when applying the Experimental Exclusion to deny coverage for PBRT to Plaintiffs and the PBRT Class.

55. UnitedHealthcare has since recognized that PBRT is not experimental "for treating prostate cancer." There were no clinical developments in the field of PBRT from the time UnitedHealthcare denied Mr. Cole's request for pre-authorization of PBRT in May 2018 to January 2019, when the New 2019 Policy took effect, and UnitedHealthcare deemed PBRT to be a proven, safe, and effective treatment for prostate cancer in persons 19 years of age or older.

F. Despite its Uniform Policy to Deny the Claims of its Beneficiaries, UnitedHealthcare's Public Initiatives Support PBRT for the Treatment of Cancer

56. In 2015, ProHEALTH Proton Center Management, LLC ("ProHealth"), an affiliate of UnitedHealthcare, received approval from the New York Public Health and Health Planning Council to construct and operate the New York Proton Center in Harlem, New York.

57. As part of the agreement with the State of New York, ProHealth pledged $15,359,260 for the New York Proton Center and became a 33 percent member in the management company that provides equipment and day-to-day administrative/nonclinical support for the project.

58. The New York Proton Center's website acknowledges their partnership with ProHealth to make PBRT more accessible to patients seeking cancer treatment, including prostate cancer.

59. Thus, during the time that the PBRT Policy was in effect, UnitedHealthcare simultaneously presented to the New York Public Health and Health Planning Council that PBRT

was an appropriate treatment for cancer while denying coverage for such treatment to its plan participants and beneficiaries.

G. The Wrongful Denials & Administrative Appeals

1. Kate Weissman

60. Ms. Weissman was born on July 6, 1985, the younger of two daughters to Bob and Cindy Weissman. She attended Dickinson College in Carlisle, Pennsylvania, where she played women's lacrosse and met Matt Eonta, a pitcher on the baseball team, with whom she graduated in 2007 and married on June 22, 2013.

61. In October 2015, at the age of 30, Ms. Weissman was diagnosed with Stage IIB squamous cell carcinoma of the cervix. She underwent traditional treatment including chemo radiation of weekly cisplatin, pelvic radiation, and tandem and ovoid brachytherapy that she completed in December, 2015, with complete clinical response.

62. Unfortunately, a PET/CT Scan, obtained on March 8, 2016, revealed two small lymph nodes at the edge of the prior treatment field in the para-aortic region, which biopsy confirmed was squamous cell carcinoma. Ms. Weissman underwent laparoscopic resection of the two lymph nodes on April 6, 2016.

63. Ms. Weissman was referred to Andrea L. Russo, M.D., Assistant Professor, Harvard Medical School, Department of Radiation Oncology, Massachusetts General Hospital ("MGH") for consideration of PBRT. Dr. Russo, along with Ms. Weissman's multi-disciplinary care team at Dana-Farber Cancer Institute ("DFCI"), determined that adjuvant radiotherapy with weekly cisplatin to the para-aortic lymph nodes, matched inferiorly to the top of her prior pelvic radiation field, would be in Ms. Weissman's best interest. Ms. Weissman's doctors concluded that PBRT, for at least a portion of the treatment course, was essential for the following reasons:

a. The para-aortic lymph nodes lied directly between both kidneys and posterior to the small bowel;

b. An IMRT plan but could not meet the bowel metrics and, therefore, Ms. Weissman was at significant risk of bowel toxicity with IMRT therapy;

c. The bowel metrics could be substantially reduced using PBRT;

d. An IMRT plan but could not meet the bone marrow metrics, which was extremely important since Ms. Weissman had received prior cisplatin and would receive additional cisplatin as a radio-sensitizing agent during treatment;

e. Published data has shown that PBRT can significantly reduce the dose to bone marrow, bladder, and small bowel compared to IMRT in patients with gynecologic cancer; and

f. A study looking at IMRT to treat para-aortic recurrences concluded there was still a 19% risk of late GI toxicity, which would be significantly reduced with PBRT since the entire bowel anterior to the treatment field would be spared.

64. Pursuant to the terms and conditions of the Interpublic Plan, Ms. Weissman's health care providers contacted UnitedHealthcare and requested prior authorization for Ms. Weissman's treatment plan, including PBRT. In a letter dated April 6, 2016, UnitedHealthcare denied coverage for Ms. Weissman's PBRT.

65. UnitedHealthcare's denial was based upon the PBRT Policy and the Experimental Exclusion. Quite clearly from the letter, UnitedHealthcare's medical director simply looked at Ms. Weissman's diagnosis of cervical cancer and then looked at the "not indicated" listed in the PBRT Policy and concluded: "You have cervix cancer. We looked at your health plan medical

criteria for radiation therapy. This treatment does not meet criteria for coverage. It has not been proven that this treatment is more effective than standard radiation for your medical condition."

66. A copy of the denial letter was mailed to Ms. Weissman and to Dr. Russo at MGH. Ms. Weissman and Dr. Russo appealed UnitedHealthcare's denial pursuant to the terms of the Interpublic Plan.

67. In a letter dated April 12, 2016, UnitedHealthcare expressed its decision to uphold its denial of coverage following review of the appeal by a UnitedHealthcare medical director, board certified in medical oncology, who determined that based on the PBRT Policy, "the requested service has not been shown to be safe and effective for [Ms. Weissman's] condition." Coverage was denied pursuant to the Experimental Exclusion. However, UnitedHealthcare stated that it was sending Ms. Weissman's case to an outside specialist in radiation oncology in order to get an expert opinion. UnitedHealthcare was certain to remind Ms. Weissman in its letter that she would be "responsible for all costs related to [the PBRT]" pending the review.

68. It should be noted that out of the 103 articles referenced in the applicable December 2015 version of the PBRT Policy, only *one* referenced squamous cell carcinomas and only *one* referenced cancers of the cervix. The first of these articles was published in 2010, five years prior to Ms. Weissman's request for PBRT. The second of these articles was published in 2003, nearly a decade-and-a-half prior to Ms. Weissman's request for PBRT. The dearth of analyzed and reviewed scientific literature found in the PBRT Policy pertaining to squamous cell and cervix carcinomas comes nowhere close to accurately capturing the state of the scientific evidence surrounding PBRT at the time Ms. Weissman made her request for PBRT in 2016.

69. In a letter dated April 13, 2016, UnitedHealthcare sent a "corrected" decision on the appeal and stated: "We are pleased to inform you that we will process the claim(s) relevant to

this service(s) accordingly." But on page two of the letter, UnitedHealthcare clarified that it would only process the claim for IMRT; that it was not reversing its denial of PBRT. In the letter, UnitedHealthcare stated that it had requested "a Board-certified independent doctor" who "specializes in radiation oncology" to review Ms. Weissman's case and determined that "there is not enough evidence . . . to show [PBRT] is effective for [her] condition." UnitedHealthcare determined that PBRT was "considered unproven under the terms of [the Interpublic Plan]."

70. Ms. Weissman and her health care providers were determined and again appealed UnitedHealthcare's denial.

71. In a letter dated April 22, 2016, UnitedHealthcare expressed its decision to uphold the denial and explained that the second appeal was reviewed by a medical director, specializing in obstetrics and gynecology, who concluded: "You have cervical cancer. … We have reviewed your health plan benefits regarding the use of [PBRT]. Based on the review, there is not enough medical evidence to show [PBRT] is effective for your condition."

72. Ms. Weissman was in a fight for her life, and neither she nor her health care providers were willing to surrender to UnitedHealthcare's unreasonable denial of coverage. In a letter dated April 27, 2016, Dr. Russo expressed her opinions as to the medical necessity for PBRT in Ms. Weissman's case. She explained that Ms. Weissman's case had been presented to the PBRT rounds at MGH, which functions as a board to allocate treatment slots for patients, given the demand for PBRT that greatly exceeds the available supply. Patients are selected for treatment based on the curative potential of the therapy and benefits of that therapy over other options. The MGH PBRT rounds authorized PBRT for Ms. Weissman at the next available treatment slot.

73. Dr. Russo pleaded with UnitedHealthcare, explaining that Ms. Weissman was "a 30-year-old woman with a curable tumor and a long life ahead of her. Proton therapy is not

considered to be experimental, investigational or unproven, given there is published data showing significant dose reductions to nearby organs at risk. There is no reason to put [Ms. Weissman] at additional risk of toxicity when we have a less toxic modality available." Dr. Russo was joined as a signatory on the April 27, 2016, letter by five other board-certified gynecological oncologists or radiation oncologists from MGH and DFCI. Five of the physicians are professors at Harvard Medical School, and the other was once named among America's Top Doctors by Newsweek magazine.

74. UnitedHealthcare referred the appeal for a purported external independent review, which was handled by AllMed Health Care Management. In an unsigned letter dated May 5, 2016, AllMed expressed the independent reviewer's opinion that PBRT in Ms. Weissman's case was excluded under the Interpublic Plan as experimental or investigational because "there is not enough strong clinical evidence to suggest [PBRT] would change the outcome in this case." The identity of the independent reviewer was not revealed.

75. UnitedHealthcare refused to budge despite pleas on Ms. Weissman's behalf by United States Senators Elizabeth Warren and Edward Markey, and Congressman Michael Capuano.

76. UnitedHealthcare chose to rely on the PBRT Policy, the Experimental Exclusion and the opinions of its medical directors, despite their lack of requisite qualifications and expertise in medical and radiation gynecology oncology, instead of the opinions of Ms. Weissman's esteemed and properly board-certified health care providers.

77. Ms. Weissman was forced to incur a $95,000.00 expense for PBRT treatment, without any assistance from UnitedHealthcare.

78. The PBRT was a tremendous success and Ms. Weissman, now 34 years old, has been cancer free for three years, a critical mile post in her recovery since the risk of recurrence drops considerably after two years.

79. Ms. Weissman, successful in her fight for life, now pursues this fight for change, individually and on behalf of the PBRT Class Members, particularly those less fortunate and unable to bear the economic expense of PBRT treatment, so that UnitedHealthcare's insured members suffering with cancer will not have to suffer the extreme and outrageous anxiety and distress of wrongful coverage denials by UnitedHealthcare, in addition to the crippling cost of care, at a time when they should be focused on their recovery, not fighting with UnitedHealthcare.

2. Richard Cole

80. Mr. Cole was born on April 11, 1948 in Miami, Florida. He is the founder and managing partner of Cole, Scott & Kissane, one of the largest law firms in Florida. Mr. Cole received his Bachelor of Science degree in Business Administration from the University of Florida and his Juris Doctor from the University of Florida College of Law. Through his career, Mr. Cole has remained committed to serving his local community in various leadership roles in civic groups, such as the United Way of Dade County and Kiwanis Breakfast Club of Miami, as well as voluntary bar organizations and The Florida Bar.

81. Mr. Cole was diagnosed with high risk prostate cancer in April 2018. In May 2018, Mr. Cole's radiation oncologist, Dr. Marcio Fagundes of Miami Cancer Institute at Baptist Health South Florida ("MCI"), recommended that Mr. Cole undergo PBRT as an alternative to IMRT because, among other things, the likelihood of achieving a better outcome was greater for PBRT.

82. On May 30, 2018, UnitedHealthcare denied Mr. Cole's request for pre-authorization of PBRT on the grounds that it fell under the Experimental Exclusion and was prohibited by the PBRT Policy. In particular, the denial stated that:

> Based on the information submitted, your health benefit plan, and our Proton Beam Radiation Therapy Policy Number 2018T0132Y Effective Date March 1, 2018 medical policy, we determined that the health care services are not covered.
>
> The services are not eligible for coverage because your plan does not cover unproven procedures.

83. On July 8, 2018, Dr. Fagundes submitted an internal appeal on Mr. Cole's behalf, asking that UnitedHealthcare reconsider its decision to deny coverage or payment for PBRT, noting that "[t]he patient has a high risk prostate cancer based on the PSA above 20 with Gleason score 7 (3+4) and clinical stage T1c" Dr. Fagundes noted that PBRT would decrease the risks of long-term toxicity and second malignancies as a result of radiation therapy.

84. UnitedHealthcare denied Mr. Cole's first appeal.

85. On August 13, 2018, Dr. Fagundes submitted a second internal appeal on Mr. Cole's behalf, again asking that UnitedHealthcare reconsider its decision to deny coverage or payment for PBRT.

86. By letter dated August 28, 2018, UnitedHealthcare upheld its decision to deny coverage. UnitedHealthcare stated:

> It was determined that your benefit plan does not pay for this service(s). This decision is based on the UnitedHealthcare Proton Beam Radiation Therapy Medical Policy and the terms of your plan.

87. UnitedHealthcare's August 28, 2018, letter exhausted Mr. Cole's internal remedies available to challenge UnitedHealthcare's benefits denial. On December 27, 2018, Mr. Cole formally requested an external review of UnitedHealthcare's decision to deny his request for PBRT

to treat his prostate cancer. Thereafter, Mr. Cole filed an external appeal with MRIA, which is unilaterally selected by UnitedHealthcare and which upheld the denial based on the Experimental Exclusion and the PBRT Policy.

88. On January 7, 2019, Mr. Cole received a letter from MRIA accepting his external review request and requiring that he submit all pertinent information he wanted considered by the IRO.

89. In compliance with MRIA's January 7th letter, Mr. Cole, by and through counsel, wrote to MRIA on January 24, 2019, requesting that UnitedHealthcare's denial of coverage for PBRT be overturned. In the letter, Mr. Cole's counsel included evidence, such as the New 2019 Policy, an updated report from Dr. Fagundes, and documents evincing UnitedHealthcare's public support for PBRT in the State of New York, in support of Mr. Cole's position that PBRT is not experimental or investigational.

90. Dr. Fagundes's updated report concluded that Mr. Cole has an undetectable amount of prostate-specific antigen, a result consistent with the efficacy of "combined androgen deprivation therapy and PBRT."

91. As part of Mr. Cole's external appeal process with MRIA, Dr. Fagundes wrote UnitedHealthcare a letter dated January 18, 2019, to support Mr. Cole's request for coverage. In the letter, Dr. Fagundes cited to peer-reviewed studies that demonstrate the efficacy of PBRT. Dr. Fagundes requested that UnitedHealthcare "reconsider approval for proton therapy" and noted that PBRT "significantly reduces radiation dose to normal rectal, bladder, and uninvolved tissue (10)."

92. Dr. Fagundes's letter also asked that UnitedHealthcare overturn its decision because of the FDA's approval of proton therapy on February 22, 1988. He further stated that Mr.

Cole "meets every criterion as defined by the FDA for appropriateness of use and therefore designating [PBRT] as experimental is fallacious, inaccurate, and contrary to the public record."

93. Notably, in denying coverage, UnitedHealthcare failed to discuss or even acknowledge the information provided by Dr. Fagundes supporting PBRT, including the many studies verifying its safety and efficacy. Thus, UnitedHealthcare provided Mr. Cole with no basis for its negative coverage determination aside from its reliance – to the exclusion of all contrary evidence – on UnitedHealthcare's pre-existing policy that PBRT falls under the Experimental Exclusion.

94. Moreover, despite the substantial support for PBRT provided to MRIA, and UnitedHealthcare's change in policy with respect to prostate cancer, on February 4, 2019, MRIA rejected Mr. Cole's request for reconsideration of its denial and concluded that PBRT was not covered. MRIA upheld UnitedHealthcare's decision to deny coverage of PBRT to Plaintiff under the old UnitedHealthcare PBRT Policy.

95. Notwithstanding UHC's denial of coverage, Mr. Cole proceeded to have PBRT, with very positive results. Mr. Cole paid approximately $85,000 for the treatment out-of-pocket.

3. Zachary Rizzuto

96. Mr. Rizzuto was born on July 11, 1980, and married Melissa (Garlit) Rizzuto on September 8, 2007. Mr. and Mrs. Rizzuto are well-educated professionals. Mr. Rizzuto obtained a Bachelor's Degree in Computer Information Systems from James Madison University. Mrs. Rizzuto obtained a Bachelor's Degree in Telecommunications and Mass Media from Temple University, a Master of Science in Communications from Florida State University, and a doctorate in Education, Curriculum and Instruction at the University of Florida. They were successful in finding employment in their chosen fields and established their home in Fort Myers, Florida.

97. In September 2016, Mr. and Mrs. Rizzuto learned that Mrs. Rizzuto was pregnant with their first child, Roxanne, who was born on May 24, 2017. Life seemed ideal.

98. While Mrs. Rizzuto was pregnant with Roxanne, however, Mr. Rizzuto began to experience absence seizures. He was unaware that he was having seizures but Mrs. Rizzuto would observe his erratic behavior. An MRI ultimately led to the diagnosis, on August 14, 2017, that Mr. Rizzuto had brain cancer.

99. A brain biopsy surgery, on August 23, 2017, confirmed the diagnosis. While Mr. and Mrs. Rizzuto were dealing with the adjustments to being first time parents, they were now forced to confront this life-shattering diagnosis. One week later, Hurricane Irma made landfall in the Florida Keys and swept across the state, inflicting further damage on Fort Myers, much like the diagnosis that befell the Rizzuto family.

100. Mr. Rizzuto's treatment plan called for a craniotomy, which was performed on December 1, 2017, where the oncological surgeon attempted to remove as much of the brain tumor as possible. On Christmas Eve, December 24, 2017, Mr. Rizzuto unfortunately learned that he would have to undergo a second craniotomy on January 31, 2018, to remove more of the tumor because there were some higher grade cancer cells present in the tumor they removed.

101. Mr. Rizzuto suffered some cognitive deficits, fatigue, loss of peripheral vision and other sensory affects as a result of the craniotomies. That is particularly why Mrs. Rizzuto was encouraged when his radiation oncologist, Robert Lustig, M.D., Chief, Clinical Operations, Radiation Oncology, and Professor of Clinical Radiation Oncology at the University of Pennsylvania, recommended PBRT.

102. Mr. Rizzuto was diagnosed with anaplastic astrocytoma, a rare malignant brain tumor. His oncologists believed that Mr. Rizzuto would benefit from PBRT because it was safer

than traditional radiation and would spare Mr. Rizzuto's healthy brain tissue on his dominant side. Traditional radiation would cast a wider sphere of radiation and likely cause too much damage to healthy brain tissue and diminish long term quality of life. Mr. and Mrs. Rizzuto were concerned about Mr. Rizzuto experiencing any further neurocognitive deficits. They were all in favor of proton beam therapy. Mr. Rizzuto's oncological team submitted a request to UnitedHealthcare for prior authorization to proceed with the PBRT on February 15, 2018.

103. Mr. and Mrs. Rizzuto spent the money to fly to the University of Pennsylvania. Unfortunately, Mr. Rizzuto learned that UnitedHealthcare had denied coverage while meeting with the oncological team.

104. In a letter dated February 21, 2018, UnitedHealthcare denied coverage for Mr. Rizzuto's PBRT based upon the PBRT Policy, and the Experimental Exclusion. Despite the Hertz Plan requirement that UnitedHealthcare provide its members with scientific or clinical reasons in the event of an adverse coverage determination, the denial letter ambiguously stated, "the specific clinical reason for [UnitedHealthcare's] decision: 9."

105. On February 27, 2018, Dr. Lustig appealed to UnitedHealthcare, stating:

> Proton therapy for brain cancer is a treatment option that involves using a focused beam of proton particles to kill diseased, cancerous tissues. Capable of delivering precise and higher doses of radiation, proton therapy treatment for brain tumors targets tumor cells while significantly reducing the damage of healthy tissue surrounding the brain. According to the American Society of Radiation Oncology "PBRT is neither a new nor an experimental technology for treating cancer with radiation: It is approved by the FDA." …
>
> The patient is a 37 year old male who has undergone a resection of a right temporal anaplastic astrocytoma, IDH mutated. … Proton radiation to the tumor bed in the right temporal lobe will avoid any radiation to the left temporal lobe including the dominant left hippocampus. Hippocampal sparing has all ready [sic] shown to be important in maintaining neurocognitive function. Avoiding any radiation to the entire left hemisphere will also I [sic] avoid any

> radiation to the speech center. In my medical opinion proton beam radiation is the most appropriate radiation treatment for Mr. Rizzuto.

106. Dr. Lustig's appeal was supplemented on February 28, 2018, by Stephen Bagley, M.D., Division of Hematology/Oncology, Brain Tumor Center, and Assistant Professor at the University of Pennsylvania, who stated:

> From my perspective as his treating medical oncologist, I strongly support the decision to use proton therapy for this patient, and it is my medical opinion that this is the most appropriate treatment for him.
> … [P]roton therapy significantly reduces the damage of healthy brain tissue surrounding the tumor, is approved by the FDA, and per the American Society of Radiation Oncology, is not considered new or experimental. In addition, I will be treating Mr. Rizzuto with temozolomide concurrently with his radiation …. Thus, in addition to the multiple reasons for using protons outlined by Dr. Lustig in his letter, the necessity of adding chemotherapy in Mr. Rizzuto's case adds further rationale for using protons in an effort to reduce collateral damage to surrounding healthy cells in the brain. In this patient who is only 37 years old and has at least several years of expected survival …, proton therapy is the preferred treatment to minimize the risk of subsequent cognitive impairment that could limit his ability to function effectively at his job and as a father and husband.

107. On March 3, 2018, UnitedHealthcare denied Dr. Lustig's appeal based upon the PBRT Policy, the Experimental Exclusion and the opinion of its medical director who specializes in Family Medicine.

108. On March 6, 2018, Mrs. Rizzuto submitted an appeal on Mr. Rizzuto's behalf. She pointed out that UnitedHealthcare refused to identify the board-certified radiation oncologist who allegedly consulted with Dr. Rabun, who is not a board certified radiation oncologist, in concluding that PBRT was "experimental and investigational or unproven." Mrs. Rizzuto also noted that the PBRT Policy provides that, "[b]ecause of these physical properties [of proton beams of radiation], PBRT may be useful when the target volume is in close proximity to one or more critical structures

and sparing the surrounding normal tissue cannot be adequately achieved with photon-based radiation therapy," and that, "NCCN [National Comprehensive Cancer Network] guidelines state that when toxicity is a concern during management of brain tumors with either a standard or high risk for recurrence, proton beam craniospinal irradiation may be considered (2017)." Finally, Mrs. Rizzuto pleaded with UnitedHealthcare, pointing out that research studies are being published that extoll the benefits of PBRT in reducing side effects of radiation (and supplying references/links for those studies), and how PBRT in Mr. Rizzuto's case would protect him from long term side effects with "staying focused, thinking critically, accessing short term memory, and applying intellectual capabilities," all of which are "critical needs in order to return to his full-time professional position … and as a father of an infant."

109. In a letter dated March 8, 2018, and a "corrected" letter dated March 9, 2018, UnitedHealthcare again denied Mrs. Rizzuto's appeal based upon the PBRT Policy, the Experimental Exclusion and the opinion of its medical director, this time who specializes in Internal Medicine.

110. The Rizzutos and Mr. Rizzuto's doctors pleaded with UnitedHealthcare to reconsider its denial, but on April 10, 2018, UnitedHealthcare stated that "all appeal rights available with UnitedHealthcare have previously been exhausted," and that UnitedHealthcare's "original determination remains unchanged." However, the matter was referred to Medical Review Institute of America ("MRIA") a so-called Independent Review Organization ("IRO")-on April 11, 2018, and on April 13, 2018, MRIA upheld UnitedHealthcare's denial because Mr. Rizzuto purportedly "does not meet the UnitedHealthcare policy for Proton Beam Radiation therapy criteria for coverage of proton beam radiation therapy."

111. In response to UnitedHealthcare's serial denials, Mrs. Rizzuto prepared a 32-page document (not including the table of contents and addendum), dated May 20, 2018, entitled "Urgent Expedited Request for Reconsideration," and directed to UnitedHealthcare's Central Escalation Unit and copies to a variety of persons at UnitedHealthcare with the ability to step up and reverse UnitedHealthcare's wrongful denial. She explained Mr. Rizzuto's history of "high-grade brain tumor: anaplastic astrocytoma" that "belongs to a group of brain tumors called 'gliomas,'" an "aggressive and fast-moving tumor," "located deep within his temporal lobe, which is a part of the cortex." She explained her concern that "[d]amage to the cortex can result in the person no longer being able to walk, talk, think, speak or remember," and how "[t]he type of radiation least likely to damage the surrounding cortex is called proton beam radiation (PBRT)." She summarized how and why Mr. Rizzuto's oncology team came to the conclusion that PBRT was the medically necessary course of treatment and the safer, more effective form of radiation. Over the course of the 32 pages, Mrs. Rizzuto cogently laid out her husband's appeal; cited to another instance where UnitedHealthcare reversed its denial and approved PBRT for treatment of a member's glioma; summarized the UnitedHealthcare in-network doctors who endorsed PBRT; laid out in detail the benefits of PBRT in avoiding brain damage, secondary cancers and other side effects; cited to recent peer review studies and industry standards and guidelines endorsing the safety and efficacy of PBRT; and pointed out the flaws in UnitedHealthcare's denials, using language from the Hertz Plan and from the PBRT Policy.

112. Among the glaring defects Mrs. Rizzuto highlighted in this appeal submission is that out of 98 articles referenced in the March 2018 version of the PBRT Policy, only ***one*** referenced brain carcinomas. This one article was a study published in 2002, more than a decade-and-a-half prior to Mr. Rizzuto's request for PBRT. Even more stunning is that in the very next

sentence in the PBRT Policy, the Policy acknowledges that the "NCCN guidelines state that when toxicity is a concern during management of brain tumors with either a standard or high risk for recurrence, proton beam craniospinal irradiation may be considered (2017)."

113. This conclusion of the 2017 updated NCCN guidelines comported with yet another study published in 2018, and submitted by Mrs. Rizzuto in her 32-page submission to UnitedHealthcare: Petr, J., et al., *Photon vs. proton radiochemotherapy: Effects on brain tissue volume and perfusion*, RADIOTHER. ONCOL. 128(1):121-127 (Jul. 2018) (concluding that proton therapy may reduce brain-volume loss when compared to photon therapy). The dearth of analyzed and reviewed scientific literature found in the PBRT Policy pertaining to brain carcinomas comes nowhere close to accurately capturing the state of the scientific evidence surrounding PBRT at the time Mr. Rizzuto made his request for PBRT in 2018. For example, although the PBRT Policy claims to have considered the American Society for Radiation Oncology's (ASTRO)—an evidence-based physician specialty society—2017 updates to its radiation treatment guidelines it blatantly ignores a critical and dispositive update to this guideline. ASTRO updated its model insurance coverage policy in 2017 detailing additional indications that would underpin a finding that PBRT would be medically necessary for a given cancer diagnosis, including a statement that PBRT should be considered medically necessary "in instances where sparing the surrounding normal tissue cannot be adequately achieved with photon based radiotherapy and is of added clinical benefit to the patient."

114. Despite listing the 2017 updates to the ASTRO and NCCN guidelines in its PBRT Policy, UnitedHealthcare appears to have intentionally ignored the conclusions of the medical community that PBRT was within the scope of the "Generally Accepted Standards of Medical Practice" for Mr. Rizzuto's diagnosis.

115. Richard J. Migliori, M.D., Executive Vice President and Chief Medical Officer of UnitedHealth Group Incorporated, UnitedHealthcare's parent company, responded on May 24, 2018, acknowledging that "Mrs. Rizzuto expressed concerns regarding the denial of the request for coverage of proton beam radiation therapy," "the appeals process, the qualifications of the physicians involved with the appeals and the UnitedHealthcare (UHC) Medical Policy for Proton Beam Radiation Therapy (PBRT)." Nonetheless, Dr. Migliori explained how "[u]nproven services are not covered because of the potential risk of harm," and that "UHC Medical Policy considers PBRT unproven and not more effective than standard radiation for treatment of [Mr. Rizzuto's] condition." Although he failed to address the points raised in Mrs. Rizzuto's 32-page submission, Dr. Migliori concluded that "a full and fair review process has occurred in your case."

116. After UnitedHealthcare turned its back on them, Mr. and Mrs. Rizzuto swallowed their pride and started a Go Fund Me page, which raised the $126,000 needed for Mr. Rizzuto to undergo the prescribed PBRT.

117. Today, Mr. Rizzuto's tumor is currently stable and being re-checked every three months. He is currently looking for a new job after resigning his position with Hertz Corporation to focus on reducing stress, healing, and making up for lost time as a new dad.

UNITEDHEALTHCARE'S ERISA VIOLATIONS

118. As the claims administrator vested with responsibility for making final benefit determinations, and responsible for interpreting and administering the Plans and similar UnitedHealthcare plans issued nationwide, UnitedHealthcare is an ERISA fiduciary.

119. As an ERISA fiduciary, UnitedHealthcare was required to discharge its duties consistent with 29 U.S.C. § 1104, which requires (among other things) that it do so "solely in the interest of the participants and beneficiaries" and for the "exclusive purpose" of "providing

benefits to participants and their beneficiaries" and paying reasonable expenses of administering the plan. It must do so with the "care, skill, prudence, and diligence" and in accordance with the terms of the plans it administers. UnitedHealthcare violated all of these requirements.

120. UnitedHealthcare violated these duties when it drafted, implemented and applied the PBRT Policy, because UnitedHealthcare relied upon outdated evidence, ignored evidence indicating that PBRT was not experimental, and unreasonably concluded that PBRT was "experimental, investigational or unproven." UnitedHealthcare then compounded that breach of duty by relying upon the PBRT Policy to deny insurance claims submitted by Plaintiffs and the PBRT Class Members in contravention of the terms of the Plans.

121. In some areas of the United States, the cost to administer PBRT far exceeds the cost for traditional IMRT for the same condition; the cost for PBRT can be double that of traditional IMRT.

122. Nonetheless, upon information and belief, UnitedHealthcare applied the PBRT Policy in Plaintiffs' case so as to not establish a precedent of covering PBRT only in areas where the cost of PBRT was comparable to traditional IMRT.

123. UnitedHealthcare did not act "solely in the interests of the participants and beneficiaries" when it denied coverage for PBRT. Rather, upon information and belief, UnitedHealthcare denied coverage for PBRT to treat cancer because, on average, PBRT is significantly more expensive than traditional IMRT or other treatments.

124. In violating its fiduciary duties, UnitedHealthcare elevated its own interests above the interests of plan participants and beneficiaries, reflecting its conflict of interest when determining whether to cover PBRT. By drafting, implementing, and applying its PBRT Policy, UnitedHealthcare sacrificed the interests of insureds like Plaintiffs and the PBRT Class so that it

could artificially decrease the number and value of claims it was required to pay from its own assets (i.e., with respect to fully insured plans and self-funded plans with stop loss provisions requiring UnitedHealthcare to cover benefits above a certain threshold) and the assets of its employer-sponsor customers (i.e., with respect to other self-funded plans); moreover, by prioritizing the assets of its employer-sponsor customers, UnitedHealthcare also advanced its own interests in retaining and expanding its business with such customers.

CLASS ACTION ALLEGATIONS

125. The proposed PBRT Class meets the requirements of Federal Rules of Civil Procedure 23(a) and 23(b).

A. The Class

126. Plaintiffs bring their claims on their own behalf and on behalf of the PBRT Class, and pursuant to Rule 23(b)(1), (b)(2), and/or (c)(4). Plaintiffs seek certification of a nationwide "PBRT Class," defined as:

> All persons covered under ERISA-governed plans, administered or insured by UnitedHealthcare, whose requests for PBRT were denied at any time within the applicable statute of limitations, or whose requests for PBRT will be denied in the future, based upon a determination by UnitedHealthcare that PBRT is not medically necessary or is experimental, investigational or unproven.

127. Excluded from the PBRT Class are: (a) Defendant, including any entity or division in which Defendant has a controlling interest, as well as its agents, representatives, officers, directors, employees, trustees, and other entities related to, or affiliated with Defendant, (b) Class Counsel, and (c) the Judge to whom this case is assigned and any members of the Judge's staff or immediate family.

128. Plaintiffs and the PBRT Class Members reserve the right under Federal Rules of Civil Procedure Rule 23(c)(l)(C) to amend or modify the Class to include greater specificity, by further division into subclasses, or by limitation to particular issues.

B. Numerosity

129. The potential members of the proposed Class as defined are so numerous that joinder of all the members of the proposed class is impracticable.

130. While the precise number of proposed Class Members has not been determined at this time, Plaintiffs are informed and believe that there are a substantial number of individuals covered under plans insured or administered by UnitedHealthcare who have been similarly affected.

131. The Class is ascertainable because its members can be readily identified using UnitedHealthcare's claims data. PBRT therapy is described with a discrete set of procedure codes under the Current Procedural Terminology ("CPT") promulgated by the American Medical Association. Accordingly, Class Members can be readily and objectively ascertained through use of records maintained by UnitedHealthcare.

132. Finally, Class members are dispersed geographically throughout the United States, such that joiner of all members is impracticable.

C. Predominance of Common Issues.

133. This action satisfies the requirements of Fed. R. Civ. P. 23(a)(2) and 23(b)(3) because questions of law and fact that have common answers predominate over questions affecting only individual Class Members. These include, without limitation:

a. Whether PBRT therapy is an "experimental or investigational" service or treatment;

b. Whether UnitedHealthcare acted as an ERISA fiduciary when it created or developed the PBRT Policy;

c. Whether Class Members' claim denials were based in whole or in part on the PBRT Policy;

d. Whether UnitedHealthcare categorically applied the PBRT Policy to deny coverage to Class Members;

e. Whether the creation, development, implementation, and application of the PBRT Policy constituted a violation of ERISA;

f. Whether Class Members are entitled to the relief sought if Plaintiffs establish liability.

D. Typicality

134. Plaintiffs' claims are typical of the claims of the proposed class. Plaintiffs are each beneficiaries of an ERISA plan administered by UnitedHealthcare, they each submitted a claim for coverage of PBRT for treatment of cancer, and, like other Class members, UHC denied their claim based on the PBRT Policy. Plaintiffs and all members of the Class are similarly affected by UnitedHealthcare's wrongful conduct.

E. Adequacy of Representation

135. Plaintiffs will fairly and adequately represent and protect the interests of the members of the proposed class. Counsel who represent Plaintiffs are competent and experienced in litigating large and complex class actions.

F. Superiority of Class Action

136. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(1) because the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications that could establish incompatible standards of conduct for UnitedHealthcare with respect to its application of the PBRT Policy and the administration and review of requests for pre-authorization or reimbursement of PBRT for the treatment of cancer.

137. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(2) because by applying a uniform policy to deny PBRT as "experimental," "investigational," or "unproven," UnitedHealthcare has acted and refused to act on grounds that apply generally to the Class, thereby requiring the Court's imposition of uniform relief to ensure compatible standards of conduct towards Class members, and making final injunctive relief or corresponding declaratory relief appropriate respecting the proposed Class as a whole.

138. The conduct of this action as a class action presents far fewer management difficulties, far better conserves judicial resources and the parties' resources, and far more effectively protects the rights of each Class member than would piecemeal litigation. Compared to the expense, burdens, inconsistencies, economic infeasibility, and inefficiencies of individualized litigation, the challenges of managing this action as a class action are substantially outweighed by the benefits to the legitimate interests of the parties, the court, and the public of class treatment in this court, making class adjudication superior to other alternatives, under Fed. R. Civ. P. 23(b)(3)(D).

139. Plaintiffs are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

FIRST CLAIM FOR RELIEF
For Declaratory Relief, Injunctive Relief
and Other Equitable Relief, and Attorneys' Fees
on behalf of the Plaintiffs and the PBRT Class
(29 U.S.C. §§ 1132(a)(3), (g))
(as to the UnitedHealthcare Defendants)

140. Plaintiffs incorporate by reference each and every one of the preceding paragraphs as if fully stated herein.

141. As set forth herein, Plaintiffs and the PBRT Class are participants in or beneficiaries of health benefit plans administered or underwritten by UnitedHealthcare and governed by ERISA.

142. UnitedHealthcare acts as an ERISA fiduciary with respect to the administration and claims decisions of the group health benefit plan it issues to employers, such as the Plans and the PBRT Class Plans, within the meaning of 29 U.S.C. § 1109(a) and 1002(21)(A). With respect to these plans, UnitedHealthcare exercises discretionary authority or control respecting management of the plans, and exercises authority or control respecting management or disposition of the plans' assets. UnitedHealthcare has the authority, and actually exercises the authority, to fund plans or administer self-funded plans (like the Plans), make decisions on claims for benefits and appeals thereof, and to write checks for benefits.

143. As an ERISA fiduciary, UnitedHealthcare must act with the utmost prudence and loyalty in communicating to plan participants and beneficiaries and in administering their claims under the plan, and must otherwise comply with the requirements of ERISA, and with terms and conditions of its ERISA plans themselves, in making benefit determinations and processing claims on behalf of plan participants and beneficiaries.

144. As the entity responsible for making medical benefit determinations under the plans and the PBRT Class members' similar plans, and responsible for developing internal practices and policies to facilitate such determinations, UnitedHealthcare is an ERISA fiduciary.

145. As an ERISA fiduciary, and pursuant to 29 U.S.C. § 1104(a), UnitedHealthcare is required to discharge its duties "solely in the interests of the participants and beneficiaries" and for the "exclusive purpose of providing benefits to participants and their beneficiaries" and paying "reasonable expenses of administering the plan." UnitedHealthcare must do so with reasonable "care, skill, prudence, and diligence" and in accordance with the terms of the plans it administers. UnitedHealthcare must conform its conduct to a fiduciary duty of loyalty and may not make misrepresentations to its insureds.

146. UnitedHealthcare violated these duties by adopting, implementing, and applying a policy to deny coverage for PBRT based on the Experimental Exclusion under its Plans, when such a finding was contrary to generally accepted practices and to the terms of the Plans. In particular, prior to the New 2019 Policy taking effect, UnitedHealthcare ignored current evidence, and widespread acceptance of PBRT as a safe and effective treatment for prostate cancer in improperly applying the Experimental Exclusion to PBRT.

147. In doing so, UnitedHealthcare did not act "solely in the interests of the participants and beneficiaries" for the "exclusive purpose" of "providing benefits." UnitedHealthcare did not utilize the "care, skill, prudence, and diligence" of a "prudent man" acting in a similar capacity. UnitedHealthcare did not act in accordance with the terms of the Plans and other UnitedHealthcare plans, all of which contain the Experimental Exclusion.

148. Instead, UnitedHealthcare elevated its own interests and those of its corporate affiliates above the interests of plan participants and beneficiaries. By applying an unreliable and outdated medical policy to PBRT claims, UnitedHealthcare artificially decreased the number and value of covered claims thereby benefiting its corporate affiliates at the expense of insureds.

149. In some areas of the United States, the cost to administer PBRT far exceeds the cost for traditional IMRT for the same condition; the cost for PBRT can be double that of traditional IMRT.

150. UnitedHealthcare did not act "solely in the interests of the participants and beneficiaries" when it denied coverage for PBRT. Rather, upon information and belief, UnitedHealthcare denied coverage for PBRT to treat cancer due to its average higher cost throughout the nation. Although the cost of PBRT may be comparable to traditional IMRT in some areas, upon information and belief, UnitedHealthcare nonetheless continued and continues

to apply the PBRT Policy uniformly nationwide so as to not establish a precedent of covering PBRT only in areas where the cost of PBRT is comparable to traditional IMRT.

151. UnitedHealthcare's decision to implement the New 2019 Policy – without any recent clinical developments – and acknowledge that PBRT is no longer experimental or investigational, demonstrates that UnitedHealthcare arbitrarily applied the PBRT Policy prior to January 1, 2019.

152. Plaintiffs and the PBRT Class Members have been harmed by UnitedHealthcare's breaches of fiduciary duty because their claims have been subjected improperly to the Experimental Exclusion, leading to denials of coverage for PBRT, when PBRT is actually a Covered Health Care Service within the definition of the UnitedHealthcare plans.

153. In acting and failing to act as described above, UnitedHealthcare has breached its fiduciary duties.

SECOND CLAIM FOR RELIEF
For Benefits Due and Clarification of Rights, and Attorneys' Fees
on behalf of the Plaintiffs and the PBRT Class
(29 U.S.C. §§ 1132(a)(1)(B), (g))
(as to All Defendants)

154. Plaintiffs incorporate by reference each and every one of the preceding paragraphs as if fully stated herein.

155. Under ERISA, UnitedHealthcare must comply with the terms and conditions of its ERISA plans in making benefit determinations and processing claims on behalf of its insureds.

156. As set forth herein, Plaintiffs and the PBRT Class Members were at all relevant times Plan participants, and members and beneficiaries of the health benefit plans administered by UnitedHealthcare and governed by ERISA.

157. Under the terms of the Plans and applicable law, UnitedHealthcare was required to pay for all medically necessary treatment for Plaintiffs and the PBRT Class.

158. While covered under the Plans, Plaintiffs and the PBRT Class were entitled to benefits under the terms and conditions of the Plans, including coverage for PBRT when Plaintiffs and the PBRT Class Members suffered cancer for which each of their treating providers determined PBRT was medically necessary.

159. UnitedHealthcare improperly denied PBRT for each of the Plaintiffs and the PBRT Class Members within the applicable limitations period.

160. Plaintiffs and the PBRT Class Members performed all duties and obligations required of each of them under the Plans. Specifically, Plaintiffs and the PBRT Class Members each complied with the Plans' requirements regarding submission of claims and exhaustion of all relevant appeals and grievance procedures, except to the extent that such exhaustion would be futile.

161. To remedy UnitedHealthcare's wrongful conduct in denying Plaintiffs and the PBRT Class Members the PBRT recommended by their providers as excluded services pursuant to UnitedHealthcare's Experimental Exclusion and PBRT Policy, Plaintiffs seek an order clarifying that application of that Policy to deny them medically-necessary PRBT violated the plain terms of the Plans, as regulated by ERISA and implementing regulations incorporated into the Plans and enjoining UnitedHealthcare from applying the Policy to claims for PRBT in the future.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs and the PBRT Class Members request relief as follows:

As to the First Claim for Relief

1. Certification of the proposed PBRT Class, appointment of Kate Weissman, Richard Cole and Zachary Rizzuto to represent the proposed PRBT Class, and designation of Plaintiffs' Counsel as Class Counsel;
2. Entry of an injunction ordering UnitedHealthcare to:
    a. Retract its categorical denials of PBRT prior authorization requests and/or claims;
    b. Provide notice to all PBRT Class Members who have had prior authorization requests or claims for PBRT denied;
    c. Re-evaluate all prior authorization requests or claims for PBRT by Plaintiffs and the PBRT Class Members under an ERISA-compliant procedure and, where warranted, reimburse Plaintiffs and the PBRT Class Members for amounts incurred for PBRT as a result of coverage denials in violation of ERISA; and
    d. Account for and disgorge any profits UnitedHealthcare may have realized by virtue of its improperly denied claims and violations of ERISA.

As to the Second Claim for Relief

3. An Order awarding Plaintiffs and the PBRT Class Members the amounts owed to them for PBRT;
4. In the alternative, entry of an injunction ordering UnitedHealthcare to:

a. Retract its categorical denials of PBRT prior authorization requests and/or claims;

b. Provide notice to all PBRT Class Members who have had prior authorization requests or claims for PBRT denied;

c. Re-evaluate all prior authorization requests or claims for PBRT by Plaintiffs and the PBRT Class Members under an ERISA-compliant procedure and, where warranted, reimburse Plaintiffs and the PBRT Class Members for amounts incurred for PBRT as a result of coverage denials in violation of ERISA; and

d. Account for and disgorge any profits UnitedHealthcare may have realized by virtue of its improperly denied claims and violations of ERISA.

As to Both Claims for Relief

5. An Order that UnitedHealthcare create a common fund from which it will make payment of any unpaid benefits, with interest, owed Plaintiffs and the PBRT Class Members;

6. Such other equitable and remedial relief as the Court may deem appropriate;

7. Payment of pre-judgment and post-judgment interest as allowed under ERISA;

8. Attorneys' fees and costs in an amount to be proven, which Plaintiffs and the PBRT Class Members are entitled to have paid by UnitedHealthcare pursuant to 29 U.S.C. § 1132(g)(1).

Dated: May 15, 2020

KATE WEISSMAN; RICHARD COLE and ZACHARY RIZZUTO, Plaintiffs and the Putative Class
By Their Attorneys,

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Certificate of Service

I certify that on May 15, 2020, a copy of this document was electronically filed through the ECF system and will be sent electronically to all persons identified in the Notice of Electronic Filing, and that paper copies will be sent to those indicated as nonregistered participants.

/s/ Mala M. Rafik
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